

(Amoxicillin for Oral Suspension USP 250 mg)

11. Stability study

BARQUE DEPARTMENT Doc. No. BQE442 Revision 00 PHARMACEUTICALS PVT. LTD. 192/3, SOKHADA388620, KHAMBHAT, DT: ANAND. (GUJ.) STABILITY STUDY PROTOCOL OF AMOXICILLIN FOR ORAL

TITLE | STABILITY STUDY PROTOCOL OF AMOXICILLIN FOR ORAL SUSPENSION USP 250 MG

Distribution	Controlled copy
COPY 1 - QA	
COPY 2 – QC	
COPY 3 – PRODUCTION	
COPY 4 - ENGINEERING	
COPY 5 – STORE	
COPY 6 – ADMINISTRATION	
COPY 7 – DIRECTOR OPERATIONS	
COPY 8 – PURCHASE	
COPY 9 – DISPATCH	
Effective Date:	Q 4 JAN 2011
	Class room training
Training Category	On job training
	Read and understood

FUNCTION	NAME	DESIGNATION	SIGNATURE	DATE
Prepared by	Darshan S. shoh	co-c-olfocer	19 -31	01/01/2011
Reviewed by	Harshud B. Palel	Q.C. Executive	Plus	02/01/2011
Approved by		Ca. C. munuago	10 Claw	pelentron
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1.0 PURPOSE:

The purpose of this stability study protocol is to conduct study of Amoxicillin For Oral Suspension USP 250mg initial three consecutive batches and one yearly batch. This is required to provide evidence on how the quality of the drug product varies with time under the influence of environmental factors such as temperature & Humidity and also enables recommended storage conditions, retest periods and shelf life to be established.

2.0 SCOPE:

This protocol gives details about generation of stability data in the given primary packaging material for Amoxicillin For Oral Suspension USP 250mg initial three consecutive batches (Initial / Non routine Stability Study) as well as for one yearly batch (Ongoing / Routine Stability Study) manufactured at Baroque Pharmaceuticals Pvt. Ltd., 192/3, Sokhada- 388 620, Khambhat. This protocol prepared with generic name of product and applicable to all brand name products having same manufacturing formula and primary packaging material.

3.0 REFERENCES:

SR. NO. CODE		TITLE
1	TRS 863	WHO Technical Report Series, No. 863, Annex 5.
2	Q1A (R2)	ICH Stability Testing of New Drug Substances and Products.

4.0 RESPONSIBILITY:

DESIGNATION	RESPONSIBILITY			
QC Officer /	To prepare stability protocol and report. To sample required quantity of			
Executive	samples as per approved protocol. To store stability sample as per storage			
	condition & chambers. Responsible for performing the analysis as per th			
- Company of the Comp	shelf life specification as well as schedule.			
Officer / Executive	To review stability protocol. To ensure that stability samples withdrawn			
QA	as per protocol. To ensure that stability study is performed as per stability			
The state of the s	protocol and SOP for stability study.			

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TITLE STABILITY STUDY PROTOCOL OF AMOXICILLIN FOR ORAL SUSPENSION USP 250 MG

DESIGNATION	RESPONSIBILITY
QC Head	To approve the stability study protocol. To conduct training.
	To review stability report data for its completeness and correctness.
	To approved stability report.
Head QA	To authorized the stability study protocol and report.

5.0 MATERIALS AND EQUIPMENT:

Stability Chambers:
 Chamber Condition: 30°C ± 2°C / 65% RH ± 5% RH
 Chamber Condition: 40°C ± 2°C / 75% RH ± 5% RH
 Others are as per the Requirement

6.0 ABBREVIATIONS AND DEFINITIONS:

6.1 ABBREVIATIONS:

TERM EXPLANATION			
TRS	Technical Report Series		
ICH	International Conference on Harmonization		
CC	Degree Centigrade		
%RH	Percentage Relative Humidity		
AC	Accelerated Condition		
The second secon	Long Term		

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6.2 **DEFINITIONS:**

TERM	EXPLANATION				
Stability	The term with respect to a drug dosage form refers to the chemical & physical integrity of the dosage unit & when appropriate, the ability of the dosage unit to maintain protection against microbial contamination.				
Accelerated testing	Studies designed to increase the rate of chemical degradation or physical change of a drug substance or drug product by using exaggerated storage conditions as part of the formal stability studies.				
Long term testing	Stability studies under the recommended storage condition for the re-test period or shelf life proposed (or approved) for labeling.				
Shelf life	The time period during which a drug product is expected to remain within the approved shelf life specification, provided that it is stored under the conditions defined on the container label.				

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TITLE STABILITY STUDY PROTOCOL OF AMOXICILLIN FOR ORAL SUSPENSION USP 250 MG

7.0 GENERAL INSTRUCTION:

7.1 Introduction

Generic Name of Product: Amoxicillin For Oral Suspension USP 250mg

Label Claim of Product:

After reconstitution each 5ml contains:

Amoxicillin USP (As Trihydrate)

Eq. to Amoxicillin 250mg Excipients Q.S

Colour: Erythrosine

7.2 Composition:

Comp	omposition: Batch Size : 10,0					100 Bottles
Sr. No.	L. C. / 5 ml (mg)	Ove INGREDIENTS Specific -ation		Item Code	A.Q.R./ B	
troom per strappy with the manufact	официпположения (* моделейных деней и моряци объектования) дене ния положения	ng Barang na Asir mangan barak sa Asir Angar	MIXING	a Allina () (Allanguan, Angel este ya Aliguak (Angelianian Angeliania Angeliania)		
1.	250.000	-	Amoxicillin Trihydrate Eq. to Amoxicillin (B)*	USP	100006U	30.000
2.	1326.370		Sucrose (Pharma Grade) (D)\$	ВР	B101027B	159.164
3.	4.000		Sodium Methyl Paraben	BP	B101022B	0.480
4.	8.500		Xanthan Gum FNCS	BP	B101051B	1.020
5.	11.100	100 may 1, 1	Sodium Benzoate	BP	B101019B	1.332
6.	2.100		Disodium EDTA	BP	B101007B	0.252
7.	27.800	-	Colloidal Anhydrous Silica	BP	B101001B	3.336
8.	0.700	-	Erythrosine Colour	IHS	B104002B	0.084
9.	36.100	-	Pineapple Flavour	IHS	B106005B	4.332

Datab Ciro

. 10 000 De44

Reference number of Batch Manufacturing Record: BQE/MFR/442

United State Pharmacopeia

BP: British Pharmacopeia

IHS: In-house Specification

L. C. /5 ml = Label Claim per 5 ml

A.Q.R/B = Actual Quantity Required Per Batch

% Ove = Overages in %.

Qtv. Req./ 5 ml = Quantity Required per 5 ml

 $(B)^* = Quantity to be calculated on the basis of its potency$

(D)\$ = Quantity to be compensated on increasing quantity of active material and its L.O.D.

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7.0 GENERAL INSTRUCTION:

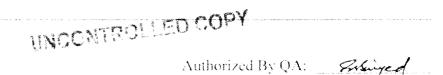
7.3 Ongoing / Routine stability study:

In case of *routine stability*, samples of one batch per product (In case of different brand name packed of same generic product, Stability study of one brand can be applicable to all brand name products having same primary packing material) per year shall be kept for *long-term stability study*.

7.4 Initial / Non routine stability study

In case of change in site, new drug product, scale up, Process validation batches, change control or any incidence required the stability study incorporate under the non routine stability study. Three consecutive batches shall be kept for Accelerated and Long Term stability study. (In case of different brand name packed of same generic product, Stability study of one brand can be applicable to all brand name products having same primary packing material for non routine study except incident and change control). The stability condition study and frequency of stability study can be modified in case of non routine stability study base on case to case requirement with reference documents.

- 7.5 Total sampling quantity to be calculated based on test wise quantity with number of test and stations analyzed. Additional two station quantity shall be kept in both conditions of stability study for additional or OOS case study (if any).
- 7.6 Samples shall be stored as per labeled storage condition until incubation. If incubation of the stability samples is delayed by 30 days or more, initial (0 month) analysis shall be done again before incubation.
- 7.7 Tolerance for testing from the due date of analysis shall ± 07 days for stability station up to 3M, ± 15 days for stability station of 6M, ±30 days for stability station of 9M and onwards. After due date sample should be stored at specified labeled storage condition.



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TITLE STABILITY STUDY PROTOCOL OF AMOXICILLIN FOR ORAL SUSPENSION USP 250 MG

7.0 GENERAL INSTRUCTION:

- 7.8 In case of delay in analysis, authorization in deviation form shall be taken from dept. head. Any significant change and out of the specification results shall be intimated to the Head-QC and to raise OOS with immediate effect. Head -QC shall investigate the out of specification (OOS) results according to the SOP.
- 7.9 If significant change or OOS findings are failing in case of Accelerated condition than it is required to increase the frequency of study from next batch. If the long term stability study failing, the joint decision shall be taken to recall of product/ Revision of Formulation/ primary packing material/ Change in storage condition Or suggested CAPA shall be followed as addressed in OOS report for further action plan.
- 7.10 In case of change in specification or test procedure of running stability study shall be handled with change control form and to be address with impact analysis and action plan case to case basis.

7.3 Training Record

7.3.1 To train personnel involved in the execution of stability study on following topics.

Purpose, Description of Detail of methodology for execution of stability study and

Acceptance criteria, Documentation.

7.4 Documentation

- 7.4.1 All documentation work shall be completed concurrently during execution of the stability study. However the protocol does not define the sequence of the test/documentation to be carried out.
- 7.4.2 Use indelible blue ink for the recording.
- 7.4.3 Do not leave any blank space in report if applicable.
- 7.4.4 Correct the wrong entry by drawing single line through incorrect data, recording the correct data and then signing and dating the change.
- 7.4.5 Enter "N/A" in space that is not applicable.
- 7.4.6 During execution of the protocol any deviation must be reported.

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8.0 VALIDATION PROGRAM

- 8.1 Primary Packaging material and source of API for Amoxicillin For Oral Suspension USP 250mg
- 8.2 Storage condition of stability study.
- 8.3 Objective, test, method of analysis, acceptance criteria and procedure for accelerated stability study.
- 8.4 Objective, test, method of analysis, acceptance criteria and procedure for long term stability study.
- 8.4 Deviations
- 8.5 OOS
- 8.6 Criteria for non routine stability study
- 8.7 Conclusion

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9.0 VALIDATION PROGRAM

9.1 Primary Packaging material and source of API for Amoxicillin For Oral Suspension USP 250mg

Primary Packing material

Sr. No.	Brand Products	Description of Primary Packing Material
1 Amoxicillin For Oral		60 ml Amber Glass Bottle
TARREST STATE OF THE STATE OF T	Suspension USP 250mg	
Label St	orage Condition of Product:	Do not store above 25°C. Keep the container
		tightly closed

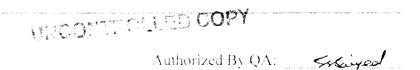
Source of API

Name of API	Name of Approved Vendor
Amoxicillin USP (As Trihydrate)	Aurobindo Pharma Ltd.

9.2 Storage condition of stability study.

Study	Storage Condition
Routine/Ongoing study	$30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \text{ RH} \pm 5\% \text{ RH}$
Non routine/Initial study	$30^{0}\text{C} \pm 2^{0}\text{C} / 65\% \text{ RH} \pm 5\% \text{ RH}$ $40^{0}\text{C} \pm 2^{0}\text{C} / 75\% \text{ RH} \pm 5\% \text{ RH}$

- 9.3 Objective: To evaluate Amoxicillin For Oral Suspension USP 250mg for a physical, chemical and microbiological property varies with time under the influence of a variety of environmental factor i.e. Accelerated condition stability study $40^{9}\text{C} \pm 2^{6}\text{C} / 75\% \text{ RH} \pm 5\% \text{ RH}$.
 - 9.3.1 Test, Acceptance criteria and method of analysis.
 - (All brand products mentioned in Annexure-IV (Manufactured from one Generic product and having same primary packaging material) have same test, MOA and specification limits under shelf life specification, so the batches shall test for stability study with respective one specification and report result could be prepared with data



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replication for all mentioned product in annexure – IV individually)

Sr. Brand Name of Product:		Test and Acceptance	Method of Analysis		
No.		Criteria			
1	Amoxicillin For Oral	Shelf Life specification	MOA No.:		
1	Suspension USP 250mg	No.: SP/BQE442SL-0	MOA/ BQE442SL-0		

^{*} For further Brand Name of Products, refer Annexure IV

9.3.2 Procedure:

- 9.3.2.1 Accelerated stability study to be performed at condition 40°C± 2^{0} C/75% RH ± 5% RH.
- 9.3.2.2 Accelerated stability study shall be performed to include initial and 3rd and 6th month (0, 3, 6M) stability study.
- 9.3.2.3 Stability study shall be followed and data to be documented as per protocol and standard operating procedure for stability study.
- 9.3.2.4 Number of test, acceptance criteria and method of analysis shall followed as per reference specification number and MOA specification number as above.
- 9.3.2.5 5% change in assay and other tests result if found out of specification shall be considered as significant change. Incase of significant change shall be evaluated with increase in frequency and out of specification results shall be evaluated by OOS. Additionally suggested CAPA of OOS shall follow to handle significant change criteria.
- 9.3.2.6 The test results shall be reported with all results, conclusion in format for report of stability study. (Refer Annexure 3)

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9.0 VALIDATION PROGRAM

9.4 Objective: To evaluate Amoxicillin For Oral Suspension USP 250mg for a physical, chemical and microbiological property varies with time under the variety of environmental factor i.e. Long term stability study 30^{0} C $\pm 2^{0}$ C and 65% RH $\pm 5\%$ RH.

9.4.1 Test, Acceptance criteria and method of analysis.

(All brand products mentioned in Annexure-IV (Manufactured from one Generic product and having same primary packaging material) have same test, MOA and specification limits under shelf life specification, so the batches shall test for stability study with respective one specification and report result could be prepared with data replication for all mentioned product in annexure – IV individually)

Sr.	Brand Name of Product:	Test and Acceptance	Method Of Analysis	
No.		Criteria		
1	Amoxicillin For Oral	Shelf Life specification	MOA No.:	
,	Suspension USP 250mg	No.: SP/BQE442SL-0	MOA/BQE442SL-0	

^{*} For further Brand Name of Products, refer Annexure IV

9.4.2 **Procedure:**

- 9.4.2.1 Real time stability study to be performed at condition $30^{\circ}\text{C} \pm 2^{\circ}\text{C}/65\%$ RH $\pm 5\%$ RH.
- 9.4.2.2 Long term storage condition should normally be every 3 months over the first year, every 6 months over the second year, and annually thereafter so, Long Term stability study shall be performed to include initial and 3, 6, 9, 12, 18 and 24 month station/Time point.
- 9.4.2.3 Stability study shall be followed and data to be documented as per protocol and standard operating procedure for stability study.
- 2.4.2.4 Number of test, acceptance criteria and method of analysis shall followed as per reference specification number and MOA specification number as above.

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9.4.2 Procedure:

- 9.4.2.5 If OOS findings are failing in case of long term stability study, the joint decision shall be taken to recall of product/ Revision of Formulation/ primary packing material/ Change in storage condition. Or suggested CAPA shall be followed as addressed in OOS report for further action plan
- 9.4.2.6 The test results shall be reported with all results, conclusion in format for report of stability study. (Refer Annexure 3)

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9.0 VALIDATION PROGRAM

9.5 **Deviations:**

Any deviations from protocol and process for stability shall be documented in the process validation report, authorized and corrected.

9.6 OOS:

If any OOS found shall be documented, investigated and authorized CAPA shall be implemented.

9.7 Non Routine Stability Study to be performed in case of:

SUSPENSION USP 250 MG

Change in formulation

Change in primary pkg. material

Change in process or critical process parameters

Change in critical mfg. equipment

Change in vendor of API

9.8 Conclusion:

Conclusion shall address in stability study report for declaration of stability of product in particular condition till specific period of study.

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10. DOCUMENT HISTORY

REVISION	DESCRIPTION OF CHANGES		DAT	-
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11. ANNEXURE

- 11.1 ANNEXURE 1: Stability Study Matrix for Accelerated Condition
- 11.2 ANNEXURE 2: Stability Study Matrix for Long Term Condition
- 11.3 ANNEXURE 3: Report Format for Stability Study
- 11.4 ANNEXURE 4: List of Applicability of Stability Study Protocol to Brand Name of Products.

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SR.	NAME OF TEST	INITIAL	ACCELERATE	D CONDITION
NO.	NAME OF IEST	0 M	3M	6M
1	DESCRIPTION	\checkmark	V	V
2	WEIGHT PER ML	V	V	V
3	рН	V	V	V
4	WATER	√	V	V
5	ASSAY (AMOXICILLIN)		V	V
6	ASSAY OF (AMOXICILLIN) AFTER RECONSTITUTION SUSPENSION WITHIN 7 DAYS	√	V	V
7	MICROBIAL PURITY	V	V	V
	SUB TOTAL	-	3	3
TOT	AL (Sub Total + OOS Samples)			

SR.	NAME OF THE	INITIAL	nd vange virjans kandidansang (1990-), philosophy hydrochi v. ni yakhilikan aktiva a v. yakhing		ONG TERM	CONDITION		THE RESIDENCE OF THE PARTY OF T
NO.	NAME OF TEST	0 M	3 M	6 M	9 M	12 M	18 M	24 M
10 market	DESCRIPTION	V	V	V	V	V	V	V
2	WEIGHT PER ML	~	\checkmark		V	V	V	V
3	рН	V	V	V	V	V	V	v.
4	WATER	V	V	\(\frac{1}{2}\)	N.	V	V.	V
5	ASSAY (AMOXICILLIN)	V	√	V	V	V	V	V
6	ASSAY OF (AMOXICILLIN) AFTER RECONSTITUTION SUSPENSION WITHIN 7 DAYS	V	V		√,'	~~~	v.	N :
7	MICROBIAL PURITY	V	1	\ \ \	V	V	V	V
1	SUB TOTAL		3	3	3	3	3	3
	OTAL (Sub Total + OOS Samples)				21 Bottles			A management of the state of th

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TITLE STABILITY STUDY REPORT FORMAT

ACCELERATED STABILITY STUDY						
Name of Product:	Amoxicitin for Oral Suspension USP 250 Mg	Storage Condition	40°C± 2°C /75% RH ± 5% RH.	Mig. Date Exo. Date	JAN 2011 DEC 2012	
Label Claim	After reconstitution each 5ml contains: Amoxicillin USP (As Trihydrate) Eq. to Amoxicillin 250mg	Packing details:	60 ml Amber Glass Bottle	Barch size Date of	10000 Boxtles	
A LONG TO THE SULPHANE AND	Excipients Q.S Colour: Erythrosine	Sample Qty.:	9 hottles	incubation	04/01/2011	
Batch No.:	BQB087.A11	API Source:	Amoxicillin USP (As Trihydrate): Aurobindo Pharma Ltd.	Period	6 Months	

Test	Specification	Initial	3 Moath	6 Month		
Description	White to Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 mi.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.		
Weight per ml	About 1.150 gm/mi	1.151 gm/ml	1.155 gm/ml	1.148 gri/mi		
pH	Between 5.0 to 7.5	5.41	5.71	5.91		
Water	NMT 3.0%	1.35%	1.51%	1,75%		
Assay (Amoxicillin)	NLT 90.0% & NMT 126.0%	100.19%	99,23%	98.32%		
Assay of (Amoxicillin) after reconstitution suspension within 7 days	NLT 90% of the stated amount of Amoxicillin	98.18%	97.68%	96.84%		
оброт регубнор (Лин Голов), у ши тите не других бай орге (ш. друг арх срудной форму, Сон били при оргену получ -	1) TAMC: NMT 10 CFU/g	1) 39 CFU/g	1) 43 CFU/g	DAR CHING		
Microbial purity	2)TYMC: NMT10 ² CFU/g	2) Nil	2) Nil	2)11		
and the second state of the second se	3) E. coli: Absent	3) Absent	3) Absent	3) Absent		
Protocoi No.	SP/BOE442	ing a series of the series of	retaalitikken 1907, tegyvooge een kiilikki kiilikatalikkii kiilikkii valkii teemakkii kokullikkii kiilikkii ki			
Conclusion: The product is found stable for 6 Months at storage condition 40°C± 2°C/75% RH ± 5% RH.						
Remark The product is found stable for 6 Months at storage condition 40°C± 2°C/75% RH±5% RH.						
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Name of	Reserved to the second	15735 BER SEL	Storage	30°C± 2°C /65% RH ± 5% RH	Mfg	. Date	JAN 2011
Product:	Amoxiciliin for Oral Suspension USP 250 Mg		Condition	ON CIT 2 C. (COTO MI IN OPERMI.	Exp.	Date	DEC 2012
The second is the second of th	After reconstitution each 5ml cont	ains:			Bate	h size	10000 Bottles
	Amoxicillin USP (As Trihydrate)		Packing details:	60 m! Amber Glass Bottle			The state of the s
Label Claim	Eq. to Amoxicillio	250mg			Date	เลโ	04/01/2011
	Excipients	Q.S	Sample Oty.:	21 hottles	inco	bation	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
	Colour: Exythrosine	and the second s	Mangas Viji	·····································	4. p. s. (8) s. p. p. 189 p. p. de (10, p.		Take yet over
Batch No.:	BQB087A11	ng - 1980 ng galandin kananggapan nagan binangganan naga binang	API Source:	Amoxicillin USP (As Tribydrate): Aurobindo Pl	harma Lid. Peri	<u>ગર્વ</u>	24 Months

Test	Specification	Initial	3 Month	6 Month	9 Month	12 Month	18 Month	24 Month
Description	White to pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 mt.	Finkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.
Weight per ml	About 1.150 gm/ml	1.151 gm/ml	1.149 gm/ml	1.151 gn/mi	1.153 gm/ml	1.155 gm/ml	1.158 gm/ml	1.162 gm/ml
pH	Between 5.0 to 7.5	5.41	5.44	5.45	5.48	5.51	5.54	5,59
Water	NMT 3.0%	1.35%	1.39%	1.42%	1,44%	1.47%	1.52%	1.55%
Assay (Amoxicillin)	NLT 90.0% & NMT 120.0%	100.19%	99.35%	99.08%	98.54%	97.98%	97.64%	97.05%

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Test	Specification	Initial	3 Month	6 Month	9 Month	12 Month	18 Month	24 Month
Assay of (Amoxicillin) after reconstitution suspension within 7 days	NLT 90% of the stated amount of Amoxicillin	98.18%	98.07%	97.85%	97.53%	97.19%	96.88%	96.52%
Microbial purity	I) TAMC: NMT 10 ² CFU/g 2)TYMC: NMT 10 ² CFU/g 3) E.coli: Absent	1) 39 CFU/g 2) Nil 3) Absent	1) 40 CFU/g 2) Nil 3) Absent	1) 41 CFU/g 2) Nil 3) Absent	1)43 CFU/g 2) Nil 3) Absent	1) 44 CFU/g 2) Nil 3) Absent	I) 46 CFU/g 2) Nii 3) Abseni	1) 48 CFU/g 2) Nil 3) Absent
Protocol No.	SP/BQE4	Chrosin Community Community of the Association of the Community of the Com	ka mendalangah kempuan menanggan menanggan sepangan pengganggan pelaban pengganggan pelaban pengganggan pelaba Pelaban pelaban		errer - 30° a 10°	B. Here was the state of the st	According to the second state of the second	oference action record communical invariance (respect process) especially as (1) a
Conclusion:				orage condition 30°			and the second s	
Remark	The produc	et is found stable f	or 24 Months at sto	orage condition 70°	C± 2°C/65% RH :	, annual relative and a rest from a transplace transplacement and a consequence of a consequence of the cons		^
Prepared By:	gr ^o		Checked By:			Approved By:	<u> </u>	
Date:	13/01/20	L	Date:	13/01/20/	3	Date:	_slailee	4

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TITLE STABILITY STUDY REPORT FORMAT

		ACCELERAT	ED STABILITY STUDY	and the second section of the second section s	processor portuges that the processor we are at any oracle processor consumption.
Name of	Name of Readust: Amosscillin for Oral Suspension USP 250 Mg		A Florida Company of the Company of	Mfg. Date	JANZOH
Product:	referencement to the contract of the contract	Condition	Storage 40°C± 2°C /75% RH± 5% RH.		DEC 2012
Label Claim	After reconstitution each 5ml contains: Amoxicillin USP (As Trihydrate) Eq. to Amoxicillin 250mg	Packing details:	60 ml Amber Glass Bottle	Batch size Date of	10000 Bottles
and the second s	Excipients Q.S Colour: Erythrosine	Sample Qty.:	9 bottles	incubation	18/01/2011
Batch No.;	BQB088A11	API Source:	Amoxicillia USP (As Trihydrate): Aurobindo Pharma Ltd.	Period	6 Months

TOST	Specification	Initial	3 Month	6 Month
Description	White to pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 mi.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.
Weight per mi	About 1.150 gm/ml	1.138 gm/ml	1.160 gm/ml	1.158 gm/ml
pil	Between 5.0 to 7.5	5.41	5.65	5.78
Water	NMT 3.0%	1.41%	1.64%	1.79%
Assay (Amoxicillin)	NLT 90.0% & NMT 120.0%	100.51%	99.17%	98.03%
Assay of (Amoxicillin) after reconstitution suspension within 7 days	NLT 90% of the stated amount of Amoxicillin	97.64%	97,49%	96.15%
Microbial purity	1) TAMC: NMT 10 ³ CFU/g 2)TYMC: NMT 10 ³ CFU/g 3) E.coli: Absent	1) 36 CFU/g 2) Nil 3) Absent	1) 42 CFU/g 2) Ni! 3) Absent	1) 46 CFU/g 2) Nil 3) Absern
Protocol No.	SP/BQE442	Errore (1907), page on the page of the pag	and the second s	and the second of the second s
Conclusion:		Months at storage condition 40°		n en
POINTS	and an an increase of the contraction of the contra	6 Months at storage condition 40°	C± 2°C/75% RH ± 5% RH.	
Prepared By:	Chacked B	1)	Approved By:	- CW3
Date: 26107	- 2011 Date:	26/07/2011	Date:	6107/2011

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	LONG TERM STABILITY STUDY								
Name of	Amoxicillin for Orai Suspension US	TO DEPOSIT	Storage	30°C± 2°C /65% RH ± 5% RH.	Mig. Date	JAN 2011			
Product:	Antoxiciini ice ceta suspciismii ce	n. The soft	Condition	DO CAL CADAGORIA DAGORIA.	Exp. Date	DEC 2012			
	After reconstitution each 5ml contai	ns:			Batch size	10000 Bonles			
	Amoxioillin USP (As Trihydrate)		Packing details:	60 ml Amber Glass Bottle					
Label Claim	Eq. to Amoxicillin	250mg		erro superior control o compression attraction and control of the	Date of	18/01/2011			
	Excipients	Q.S	Sample Oty.:	21 hottles	incubation	(DANISTORIA			
	Colour: Erythrosine		Continues Calar	ALS THERESENS		100			
Batch No.:	BQB088A11		API Source:	Amoxicillin USP (As Trihydrate): Aurobindo Pharma Ltd.	Period	24 Months			

Test	Specification	Initial	3 Month	6 Month	9 Month	12 Month	18 Month	24 Month
Description	White to pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored gramular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.
Weight per ml	About 1.150 gm/ml	1.138 gm/ml	1.147 gm/ml	1.158 gm/ml	1.162 gm/ml	1.151 gm/ml	1.155 gm/ml	1.145 gm/ml
	Between 5.0 to 7.5		5.52	5.65	5.40	5.43		5.38
Water	NMT 3.0%	1.41%	1.52%	1.54%	1.59%	1.62%	1.63%	1.68%
Assay (Amoxicillin)	NLT 90.0% & NMT 120.0%	100.51%	100,09%	99.48%	99.23%	98.64%	98.18%	97.83%

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Test	Specification	Initial	3 Month	6 Month	9 Month	12 Month	18 Month	24 Month
Assay of (Amoxicillin) after reconstitution suspension within 7 days	NLT 90% of the stated amount of Amoxicillin	97.64%	96,99%	96.37%	96.07%	95.66%	95.37%	94.98%
Microbial purity	1) TAMC: NMT 10 ³ CFU/g 2)TYMC: NMT10 ² CFU/g 3) E.coli: Absent	1) 36 CFU/g 2) Nil 3) Absent	1) 38 CFU/g 2) Nil 3) Absent	1) 40 CFU/g 2) Nii 3) Absent	1) 42 CFU/g 2) Nil 3) Absent	1) 45 CFU/g 2) Nil 3) Absem	1) 48 CFU/g 2) Nil 3) Absent	1) 49 CFU/g 2) Nil 3) Absent
Protocol No.	SP/BQE4	o commence de commença de commença de la commença d La commencia de la commença de la c	(Adam) variation interpret, and interpreted and the company of the solder (Agrical and Expension)	ing plant interstition and include repair to the statement of the statemen	k Na (seu Nordenson) ni waranaka na igi ani na ani isangan ngangan ngangan ngangan na ana na angangan nangan nga Na kanangan na ani	g Engelektromangen et ekstelektromatik film om 124000000 hann han som juangelektromannen, men ekste opposite in T		
Conclusion:	The produ	it is found stable for	or 24 Months at sto	rage condition 30°	C± 2°C/65% RH ±	= 5% RH.	e gan de despesa e e quies elegan proposition e en el de despesa e en el de despesa el despesa el de	The second difference is the contract of the second of the
Remark				mage condition 30°			an derivided delikuus assamatus, side maamaan tarpapa (part. Mi daan samaan aagamay	AND THE RESIDENCE OF THE PARTY
Prepared By:	S		Checked By:	一样。见过	entermination (Charles property and Proposition (Charles) and the Charles	Approved By:	or Deshard	Karangan
Date:	27/01/2		Date:	94/01/201	*,	Date:	/ . /	* ! D

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Name of	S. the consideration of the S. S. constitution of the S. S. C. C.		40°C± 2°C /75% RH ± 5% RH.	Mfg. Date	JAN 2011				
Product:	THE THE STATE OF T	Condition	NO CAS COLOMBIA COM MAR	Exp. Date	DEC 2012				
After reconstitution each 5ml contains:		Packing		Batch size	10000 Bottles				
or Braze of some	Amoxicillin USP (As Trihydrate)	details:	60 ml Amber Glass Bortle	9	March age				
Label Claim	Eq. to Amoxicillia 250mg		and the second of the second o	Date of	26/01/2011				
	Excipients Q.S	Sample Oty.:	9 hattles	incubation	**************************************				
	Colour: Erythrosine	A construction of the second			The state of the s				
Batch No.:	BQB089A11	API Source:	Amoxicillin USP (As Trihydrate): Aurobindo Pharma Ltd.	Period	6 Months				

Test	Specification	Initial	3 Month	6 Month
Description	White to pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.
Weight per ml	About 1.150 gm/ml	1.140 gm/mì	1.151 gm/ml	1.162 gm/ml
	Between 5.0 to 7.5	5.45	5,57	5.79
Water	NMT 3.0%	1.39%	1.68%	1.82%
Assay (Amoxicillin)	NLT 90.0% & NMT 120.0%	100.98%	99,07%	98.01%
Assay of (Amoxicillin) after reconstitution suspension within 7 days	NLT 90% of the stated amount of Amoxicillin	98.26%	97.18%	96.07%
The second secon	1) TAMC: NMT 10° CFU/g	1) 38 CFU/g	1) 43 CFU/g	1) 47 CFU/g
Microbial purity	2)TYMC: NMT102 CFU/g	2) Nil	2) Nii	2) Nil
	3) E.coli: Absent	3) Absent	3) Absent	3) Absent
Protocol No.	SP/BQE442		and the state of t	м. Магуа на настания настания и настания и том настания в реком разграфия разгова, и уку мустания на настания и
Conclusion:		5 Months at storage condition 40°		
Remark		6 Months at storage condition 40°	هوهندي موسويسيون و مهوه مد روميمون ميراه ماروهيد بالدوارات مارويات مارويات و مراويات مارويات مارويات و مراويات و مراويات مارويات و مراويات و مراوي	
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Name of Product:	Amoxicillin for Oral Suspension L	SP 250 Mg	Storage Condition	30°C± 2°C /65% RH± 5% RH.	1	JAN 2011 DEC 2012
After reconstitution each 5ml contains: Amoxicillin USP (As Trihydrate)		Packing details:	60 ml Amber Glass Bottle	Date of	10000 Bottles 26/01/2011	
	Excipients	Q.S	Sample Qty.:	21 houles	incubation	No. of the state o
Butch No.:	BQB089A11	magneticum (1995), magneticido, poi 1996 (1995) (1995) (1996) (1996) (1996) (1996) (1996) (1996) (1996) (1996)	API Source:	Amoxiciliin USP (As Trihydrate): Aurobindo Pharma Ltd.	Period	24 Months

Test	Specification	Initial	3 Mouth	6 Month	9 Month	12 Month	18 Month	24 Month
Description	White to pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 mi.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored granuler powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.	Pinkish white colored granular powder converted in to pink colored suspension on addition of water and makes the volume up to 60 ml.
Weight per mi	About 1.150 gm/ml	i.i40 gm/mi	1.143 gm/ml	1.148 gm/ml	1.153 gm/ml	1.158 gm/ml	1.157 gm/ml	1.159 gm/ml
	Between 5.0 to 7.5	5.45	5,50	5.57	5.59	5.65	5.69	\$.72
Water	NMT 3.0%	1.39%	1,43%	1.49%	1.55%	1.61%	1.65%	1.69%
Assay (Amoxicillin)	NLT 90.0% & NMT 120.0%	100.98%	100.96%	99.54%	99.02%	98.51%	98. to 0%	97.80%

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Test	Specification	Initial	3 Month	6 Month	9 Month	12 Month	18 Month	24 Month
Assay of (Amoxicillin) after reconstitution suspension within 7 days	NLT 90% of the stated amount of Amoxicillin	98.26%	97.68%	97.08%	96.64%	96.08%	95.68%	95.14%
Microbial purity	I) TAMC: NMT 10° CFU/g 2)TYMC: NMT 10° CFU/g 3) E.coli: Absent	1) 38 CFU/g 2) Nil 3) Absent	1) 39 CFU/g 2) Nil 3) Absent	1) 41 CFU/g 2) Nil 3) Absent	1) 43 CFU/g 2) Nil 3) Absem	1) 46 CFU/g 2) Nil 3) Abseni	1) 49 CFU/g 2) Nil 3) Absent	1) 50 CFU/g 2) Nil 3) Absens
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Conclusion: The product is found stable for 24 Months at storage condition 30°C± 2°C/65% RH ± 5% RH.								
Kemark	The produ	ct is found stable t	or 24 Months at ste	and the contract of the contra	C± 2°C/65% RH :			
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Date:	24/01/201	3	Dare:	24 10 1 1	L013	Date:	22/01/20	13

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STABILITY STUDY PROTOCOL OF AMOXICILLIN FOR ORAL SUSPENSION USP 250 MG
TITLE ANNEXURE 4: LIST OF APPLICABILITY OF STABILITY STUDY PROTOCOL TO BRAND NAME OF PRODUCTS

This Stability Study Protocol is prepared and approved with the Generic Name of Product. The applicability of this protocol is list out for Brand name having same manufacturing formula / process as well as primary packaging material is provided or to be updated in below table.

Sr. No.	Brand Name	Product Code	Primary packing material	Shelf life specificat ion no.	Labeled storage condition	MOA No.:	MPI No.	BPR No.	Added By	Approve d By	Authoriz ed By
	Amoxicillin For Oral Suspension USP 250 Mg	BQE442	60ml amber Glass bottle	SP/BQE 442SL-0	Store in cool dark place below 25°C.	MOA/ BQE442 SL-0		BQE/BPR (442	£.	O Bary	
h consideration and an arrange and a		The state of the s			A spread and design the control of the American Section of the Control of the Con			1 1 1	The state of the s	:	
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